

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
Baldwins
PO Box 852
Wellington 6001
NEW ZEALAND

PCT

WRITTEN OPINION OF THE INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY

(PCT Rule 66)

Date of mailing 20 DEC 2005
(day/month/year)

Applicant's or agent's file reference
JP802777/142

REPLY DUE within **TWO MONTHS**
from the above date of mailing

International application No.
PCT/NZ2004/000323

International filing date (day/month/year)
16 December 2004

Priority date (day/month/year)
19 December 2003

International Patent Classification (IPC) or both national classification and IPC
INT. CL. *A61L 15/32* (2006.01) *A61K 38/00* (2006.01) *A61L 26/00* (2006.01)
A61K 9/70 (2006.01) *A61K 38/17* (2006.01) *A61P 17/02* (2006.01)
ACTION DATE: 01 JANUARY 2006

Applicant
KERATEC LIMITED et al

1. ☒ The written opinion established by the International Searching Authority:

☒ is ☐ is not
considered to be a written opinion of the International Preliminary Examining Authority.

2. This **second** (second, etc.) opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the **Reply Due** date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the **Final Date** by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established. If no response is filed by 1 month before the **Final Date**, the international preliminary examination report will be established on the basis of this opinion.

Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least 3 months before the **Final Date** by which the international preliminary examination report must be established.

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.
For an informal communication with the examiner, see Rule 66.6.

4. The **FINAL DATE** by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 19 April 2006

Name and mailing address of the IPEA/AU
AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaaustralia.gov.au
Facsimile No. (02) 6285 3929

Authorized Officer
Arati Sardana
ARATI SARDANA
Telephone No. (02) 6283 2627

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.

PCT/NZ2004/000323

Box No. I **Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ The international application in the language in which it was filed:
- ☐ A translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1 (b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this opinion has been established on the basis of (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."*):

- ☐ the international application as originally filed/furnished
- ☒ the description: pages 1, 2, 5-20 and 24, as originally filed/furnished
pages 3 and 4, received by this Authority on 18 October 2005 with the letter of
pages , received by this Authority on with the letter of
- ☒ the claims: pages 22 and 23, as originally filed/furnished
pages , as amended (together with any statement) under Article 19,
pages 21, received by this Authority on 18 October 2005 with the letter of 18 October 2005
pages , received by this Authority on with the letter of
- ☒ the drawings: pages 1/3-3/3, as originally filed/furnished
pages , received by this Authority on with the letter of
pages , received by this Authority on with the letter of
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.

PCT/NZ2004/000323

Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 15, 18, 19, 21 and 22	YES
	Claims 1-14, 16, 17 and 20	NO
Inventive step (IS)	Claims	YES
	Claims 1-22	NO
Industrial applicability (IA)	Claims 1-22	YES
	Claims	NO

2. Citations and explanations:

CITATIONS:

D1: WO 2003/011894 ✓

D2: US 5,932,552 ✓

D3: WO 2003/103737 ✓

D4: AU 2002330798 ✓

EXPLANATION:

D1 discloses the production soluble keratin derivatives. The keratin protein fraction that is produced is intact and are S-sulfonated keratin intermediate filament proteins and S-sulfonated keratin high sulphur proteins.

D2 discloses keratin hydrogel which can be used as a wound dressing. The disulfide linkages in keratin are reformed.

D3 discloses keratin material that is S-sulfonated and enriched in intermediate filament proteins. D3 further discloses S-sulfonated keratin intermediate filament protein powder. The keratin material disclosed in D3 is used in the treatment of bone fractures.

D4 discloses the production of keratin derivatives of the present invention in the form of films, fibers, foams and adhesives and an extension of the use of these in medical materials.

NOVELTY (N) Claims: 1-14, 16, 17 and 20

Amended claims 1-8 are still directed to an intact keratin protein fraction. The phrase 'A wound treatment material' does not limit the use of the present keratin protein fraction in the treatment of wounds. The present keratin protein fraction defined in claims 1-8 is known from the disclosure of D1, D3 or D4. Similarly claim 9 directed to a fiber, film or a foam of the present keratin fraction is also not limited to when used in the treatment of wounds and is known from the disclosure of D4.

Claims 1, 10-14, 16, 17 and 20 also still lack novelty in light of the disclosure of D2 because the present intact keratin fraction as defined in claims 1, 10-14, 16, 17 and 20 is not distinguished from the intact keratin fraction of D2.

INVENTIVE STEP (IS) Claims 1-22

Claims 1-14, 16, 17 and 20 as for novelty. Claims 1-22 lack an inventive step in light of the disclosure of D1, D3 or D4 when combined with the disclosure of D2. The skilled person would formulate the wound dressing or hydrogel of D2 by substituting the keratin of D2 with keratin protein fraction of D1, D3 or D4. Therefore claims 1-22 lack an inventive step.